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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,109	01/11/2005	Francesco Tedesco	50294/016001	5428

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	
MAIL DATE	**DELIVERY MODE**
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,109	TEDESCO ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a Rule 371 continuation of PCT Serial Number PCT/EP03/078487.

Original claims 1-36 have been canceled.

New claims 37-76 have been added.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 37-49, 56, and 58, drawn to a human antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group II, claim(s) 50-54, 57, and 59, drawn to a nucleic acid that encodes a human antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group III, claim(s) 60, 62, 64, and 66, drawn to a method for the prevention of complement hyperactivation comprising administering an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group IV, claim(s) 61, 63, 65, and 67, drawn to a method for the prevention of complement hyperactivation comprising administering a nucleic acid encoding an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments..

Group V, claim(s) 68, drawn to a method for setting up an animal model comprising administering a method for the prevention of complement hyperactivation comprising administering an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group VI, claim(s) 69, drawn to a method for the prevention of complement hyperactivation comprising administering a nucleic acid encoding an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group VII, claim(s) 70, drawn to a method of selecting anti-C5 antibodies comprising binding antibodies to C5 and inhibiting SRBC hemolysis.

Group VIII, claim(s) 71, drawn to a process for preparing antibodies to activated C5 using a nucleic acid encoding an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group IX, claim(s) 72, drawn to a kit comprising an anti-C5 antibody that binds to amino acid residues 731-740.

Group X, claim(s) 73, drawn to a kit comprising a nucleic acid encoding an anti-C5 antibody that binds to amino acid residues 731-740.

Group XI, claim(s) 74, drawn to a process for the selection if inhibitors of C5 conversion using an antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

Group XII, claim(s) 75, drawn to a peptide comprising SEQ ID NO: 15.

Group XIII, claim(s) 76, drawn to a process for the selection if inhibitors of C5 conversion using a peptide comprising SEQ ID NO: 15.

Group XIV, claim(s) 55, drawn to a non-human transgenic animal comprising a nucleic acid that encodes a human antibody to the sequence defined by amino acid residues 731-740 of activated complement component C5, wherein said antibody inhibits the generation of the C5a and C5b fragments.

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims are drawn to antibodies that block the conversion of complement component C5 to the active fragments C5a and C5b. Fitch (Circulation [1999] 100:2499-2506; cited on form PTO-1449) teaches a pharmaceutical composition comprising the humanized form of the antibody 5G1.1, which blocks the conversion of C5 to C5a and C5b, commensurate with the composition of claim 56. Accordingly, the claims are not so linked by a special technical feature so as to constitute a single inventive concept.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from**

or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
June 25, 2007

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER